K093787

iGuide CAPPA
510(k) Summary of Safety and Effectiveness

MAR 11 2010

I. Manufacturer

CAS Innovations GmbH & Co. KG
Heusteg 47
91056 Erlangen
Germany

II. Contact Person:

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Quality Systems Director
CAS Innovations Inc.
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III. Device Name and Classification:

Trade Name:	iGuide CAPPA
Common Name:	Computer-assisted image-guided surgery system
Classification Name:	Computer Tomography X-ray System
Classification Panel:	Interventional Radiology
CFR Section:	21 CFR 892.1750
Device Class:	Class II
Product Code:	JAK

IV. Date Prepared

November 20, 2009

V. Device Description

iGuide CAPPA is a navigation system that assists in the planning of different trajectories to selected targets and the navigated positioning of tools (e.g. biopsy needles, injection needles for vertebroplasty and kyphoplasty procedures) inside these targets. The navigation system can be used within the scope of interventional radiology.

Navigation System:

The navigation station consists of an industrial PC with an integrated touch-screen as user interface and specific navigation software. The PC is mounted on a mobile rack. For image acquisition the navigation system is connected to an imaging system (CT, MRT, C-Arm). A DICOM network application using the DICOM standard protocol provides the communication between the navigation system and the imaging system.

In order to track the navigation devices, an electromagnetic (EM) tracking system is used. This tracking system consists of a field generator producing an alternating electromagnetic field. The EM field induces voltage in the small coils implemented in the tips of the navigation devices. The voltage is measured by the EM tracking system and used to calculate the current position and orientation of the coil, thus determining the sensor's coordinates in five degrees of freedom (DoF).

The navigation hardware (PC, monitor, rack and tracking system) is combined to form NaviBase, a hardware and software platform for navigation applications.

Accessory Needles:

Electromagnetic needles with small coils embedded in their tips are used as navigation devices. For image-to-patient registration a reference plate (RP) is used. This plate makes it possible to map the patient image data to the actual physical data.

Motion Sensor:

Residual patient motion is monitored by an additionally tracked device (motion sensor) affixed to the patient's skin. The tracking system detects the motion sensor and sends its position relative to the RP to the navigation system. Patient motion is visualized on the monitor enabling the radiologist to recognize the motion and react accordingly.

VI. Intended Use

iGuide CAPPA is intended to be an intraoperative image guided computer assisted navigation system for minimally invasive interventions for interventional radiology. iGuide CAPPA can be used in combination with imaging systems that create a 3D-based model of the anatomy, like Computer Tomography (CT) or C-Arm systems.

It displays the simulated image of a tracked device (needle) on a computer monitor screen that shows images of anatomic relevant regions of the patient. The system also allows the planning of trajectories and displays the planning information together with

the simulated image of a tracked needle on a computer monitor screen. At the same time movements of the patient are taking into account.

The device is intended to be used in clinical applications and for anatomic structures where computer tomography or c-arm is currently used for visualizing such devices.

VII. Substantial Equivalence

iGuide CAPPA software and hardware are identical to those of NavStationIrad EMT, also manufactured by CAS innovations GmbH & Co. KG and cleared by premarket notification number K080624. The accessory needles for biopsy and RF ablation procedures cleared by K080624 can also be used with iGuide CAPPA.

The reason for this 510(k) submission is the addition of a new accessory needle, the Electromagnetic Tracking Needle Vertebroplasty. This needle is intended for injection of bone cement (not included) for the fixation of pathological fractures of the vertebral body using vertebroplasty and kyphoplasty procedures. It is substantially equivalent to the Introduction Needles and Stylets for vertebroplasty and kyphoplasty manufactured by Stryker Instruments, classified as OAR, 21 CFR 888.4200 (class 1). The electromagnetic tracking system for positioning the new needle at the target site is identical to that of the previously cleared needles included in K080624.

VIII. Labeling

Device labeling includes instructions for use containing the indications for use, clinical workflow, cautions, contraindications, warnings, and planning guidance. All information assures safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 7 2010

CAS Innovations GmbH & Co., KG
% Ms. Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Amstel 320-I, Amsterdam, NH 1017AP
NETHERLANDS

Re: K093787
Trade/Device Name: iGuide CAPPA
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, OAR, and GAA
Dated: February 2, 2010
Received: February 12, 2010

Dear Ms Scherp:

This letter corrects our substantially equivalent letter of March 11, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K093787

Device Name: iGuide CAPPA

Indications for Use:

iGuide CAPPA is intended to be an intraoperative image-guided computer-assisted navigation system for minimally invasive interventions for interventional radiology. iGuide CAPPA can be used combination with imaging systems that create a 3D-based model of the anatomy, like Computer Tomography (CT) or C-arm systems.

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The device is intended to be used in clinical applications and for anatomic structures where computer tomography or c-arm is currently used for visualizing such devices.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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